2011 Procedures Adult Criteria

Vagal Nerve Stimulator (Custom) - UDOH[1*RIN, 2, 3, 4]

Created based on InterQual Subset: Vagal Nerve Stimulator

Version: InterQual® 2011

CLIENT:	Name	D.O.B.	ID#	GROUP#
CPT/ICD9:	Code	Facility	Service Date	
PROVIDER:	Name		ID#	Phone#
	Signature		Date	

ICD-9-CM: 01.20, 02.93, 86.94, 86.96, 86.97, 86.98

INDICATIONS (choose one and see below)

☐ 100 Known seizure disorder

☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Known seizure disorder **[One]**[5*RIN, 6, 7]

- ☐ 110 Initial placement of VNS Stimulator **[One]**
  - ☐ 111 Partial onset seizures refractory to Rx **[All]**
    - ☐ -1 Rx with ≥ 2 anticonvulsant medications[8]
    - ☐ -2 Anticonvulsant levels therapeutic
    - ☐ -3 No concurrent seizure-provoking medications[9]
    - ☐ -4 No sudden cessation of heavy alcohol use w/in 48 hrs of seizure[10]
    - ☐ -5 No intoxication due to drugs of abuse w/in 48 hours of seizure[11]
    - ☐ -6 Surgical treatment **[One]**[12]
      - ☐ A) Continued seizures after epilepsy surgery
      - ☐ B) Patient not a candidate for epilepsy surgery
- ☐ 120 Replacement of VNS Stimulator **[One]**
  - ☐ 121 Documentation from provider stating that previous VNS stimulator was found to be non-functioning at the time of battery replacement procedure 61885[13*RIN]

Notes

(1)-RIN:

Although the vagal nerve stimulator (VNS) procedure has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of refractory major depressive disorder, studies have yielded inconclusive results regarding short and long-term efficacy, and optimal patient selection issues are not yet clearly defined. In addition, the precise definition of treatment-resistant depression has not been established (Shelton et al., CNS Drugs 2010; 24(2): 131-161; Rush and Siefert, Exp Neurol 2009; 219(1): 36-43; Daban et al., J Affect Disord 2008; 110(1-2): 1-15; Rush et al., Biol Psychiatry 2005; 58(5): 347-354). For these reasons, as well as concerns about safety, many organizations, including Centers for Medicare and Medicaid (CMS), have declined to endorse or reimburse this procedure for the treatment of major depressive disorder (Shuchman, N Engl J Med 2007; 356(16): 1604-1607).

(2)-DEF:

The vagal nerve stimulator is a surgically implanted device that sends intermittent electrical pulses to the brain. The battery-operated generator (implanted in the chest wall) is attached to wires that are threaded along the carotid sheath. It is then programmed to pulse the vagal nerve at predetermined frequencies to aid in controlling seizure frequency and intensity. The precise mechanism of action is not known.

(3)

The most common postoperative side effects associated with this procedure are hoarseness, neck and throat pain, nausea, vomiting, dyspnea, and coughing; typically these resolve with time or treatment. Use of VNS, however, can worsen symptoms for patients with pre-existing obstructive sleep apnea (Marson et al., Clin Evid (Online):Jan 28;2009. pii: 1201.; Hatton et al., Anesth Analg 2006; 103(5): 1241-1249). Infection is infrequent, usually caused by *S. Aureus*, and may necessitate removal of the device if symptoms are unresponsive to antibiotic therapy (Air et al., J Neurosurg Pediatr 2009; 3(1): 73-78).

(4)

The VNS is typically activated within 4 weeks of implantation, and then programmed for strength and duration of pulsing. The amount of stimulation varies by patient, but it is usually initiated at a low level, gradually increasing to an appropriate patient-specific level. The stimulator runs continuously but is programmed to turn on and off for specific periods of time. Pulsing is not felt by the patient. Patients can be given a hand-held magnet that delivers additional stimulation, regardless of the treatment schedule, to respond to an aura or onset of an evolving seizure.

(5)-RIN:

Although the U.S. Food and Drug Administration (FDA) has approved treatment of partial onset seizures with a VNS in patients 12 years of age or older, this criteria addresses the use of VNS for patients ≥ 18 years of age.

(6)

Approximately one-third of individuals with epilepsy do not achieve seizure control with anti-epileptic medications (Milby et al., Neurotherapeutics 2009; 6(2): 228-237). Vagal nerve stimulation may be an appropriate surgical adjunct for those individuals who have failed surgery, are not candidates for resection surgery, and who continue to experience persistent seizures refractory to maximum drug therapy (Ghaemi et al., Seizure 2010:Jun;19(5):264-8.). The reported outcomes from multiple studies demonstrate an overall decrease in seizure frequency of more than 50% in approximately 40% of those implanted; in some patients, the cumulative effect improves over time (Vonck et al., Adv Tech Stand Neurosurg 2009; 34: 111-146; Lulic et al., Neurosurg Focus 2009; 27(3): E5; Milby et al., Neurotherapeutics 2009; 6(2): 228-237; Schuele and Luders, Lancet Neurol 2008; 7(6): 514-524).

(7)-POL:

HCPCS code L8680 is covered in the DRG for the inpatient services and is not prior authorized or reimbursed separately.

(8)

The International League Against Epilepsy (ILAE) has proposed that drug resistant epilepsy be defined as failure of adequate trials of 2 tolerated and appropriately chosen and used anti-epileptic medications (whether as monotherapy or in combination) to achieve sustained seizure freedom (Kwan et al., Epilepsia 2010, 51: 1069-77). No seizure frequency requirement is necessary to meet the definition; thus, an individual with 1 seizure per year can be regarded as treatment resistant. The task force defines treatment success as the complete cessation of seizures for 1 year or 3 times the longest interseizure interval during the recent active phase of epilepsy.

(9)

Prescription medications such as TCAs, antipsychotics, theophylline, and lidocaine can lower the seizure threshold. Attempts should be made to reduce or discontinue all such medications, but the risks and benefits of such an intervention need to be considered for each patient.

(10)

Sudden cessation of heavy alcohol consumption can lead to withdrawal seizures. Typical withdrawal seizures are usually self-limited, and long-term anticonvulsant treatment is not necessary (Graham et al., Principles of Addiction Medicine. 2003, 1648 p.; Hillbom et al., CNS Drugs 2003; 17(14): 1013-1030).

(11)

Intoxication with certain inhalants and stimulants can lead to seizures.

(12)

Despite attempts at curative surgery, approximately 30% of patients with refractory epilepsy will continue to experience seizure activity. The goal of curative surgery for epilepsy is for the patient to be off of all antiepileptic medications. Examples of procedures include lesional resection, lobectomy, corticectomy, and some cases of hemispheric surgery and multiple subpial transections. Palliative procedures rarely result in cessation of seizures, but may lessen the frequency or severity of seizures. Palliative surgical procedures can include some cases of hemispheric surgery, multiple subpial transections, or disconnection procedures, such as corpus callosotomy. In addition, patients who appear to have multiple seizure types arising from different brain regions and those with genetic forms of epilepsy are not considered surgical candidates. For these groups, vagal nerve stimulation may be a viable option (Spencer and Huh, Lancet Neurol 2008, 7: 525-37; van Rijckevorsel, Neuropsychiatr Dis Treat 2008, 4: 1001-19; Tellez-Zenteno et al., Brain 2005, 128: 1188-98).

(13)-RIN:

Prior authorizations will be given retroactively for code 64568, if procedure planned was "replacement of pulse generator"-61885 and code 64568 was discovered to be necessary, intraoperatively.